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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53 (c).

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<input type="checkbox"/> Additional inventors are being named on the _____ separately numbered sheets attached hereto					
TITLE OF THE INVENTION (500 characters max)					
"END CAP FOR A MICRO-SAMPLING DEVICE"					
CORRESPONDENCE ADDRESS					
Direct all correspondence to:					
<input checked="" type="checkbox"/> Customer Number		23506		Place Customer Number Bar Code Label here	
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ENCLOSED APPLICATION PARTS (check all that apply)					
<input checked="" type="checkbox"/> Specification Number of Pages		10		<input type="checkbox"/> CD(s), Number _____	
<input checked="" type="checkbox"/> Drawing(s) Number of Sheets		4		<input checked="" type="checkbox"/> Other (specify) Return Postcard	
<input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76					
METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT					
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.					
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<input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number:				50-1513	
<input checked="" type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.				FILING FEE AMOUNT (\$)	
The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.					
<input checked="" type="checkbox"/> No.					
<input type="checkbox"/> Yes, the name of the U.S. Government agency and the Government contract number are: _____					

Respectfully submitted,

SIGNATURE

Date

July 28, 2003

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REGISTRATION NO.
(if appropriate)

39,695

Docket Number:

2G02.1-150

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16235 U.S. PTO

60/490477

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Date: July 28, 2003

Signature: Vanessa Lako

APPLICATION FOR PROVISIONAL LETTERS PATENT

UNITED STATES OF AMERICA

Be it known that **Don GRIFFIN**, of 1575 Ridenour Parkway, Apt. 2319, Kennesaw; and **Jack GRIFFIS**, of 1133 Druid Lake, Decatur, both of Georgia, have invented certain new and useful improvements in an

END CAP FOR A MICRO-SAMPLING DEVICE

for which the following is a specification.

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END CAP FOR A MICRO-SAMPLING DEVICE

Technical Field

[00001] The present invention relates generally to medical devices and procedures, and more particularly to lancing devices. The invention also relates to an
5 end cap for use in conjunction with a lancing device that allows for a collection of an increased volume of blood or bodily fluid to be obtained.

Background of the Invention

[00002] Many medical procedures require puncturing of the skin, and sometimes underlying tissues, of an animal or human subject. For example, a sharp lancet tip is
10 commonly used to puncture the subject's skin for sampling of blood or other body fluid, as for example in blood glucose monitoring by diabetics. Generally, lancets are much thinner than traditional hypodermic syringe needles; and therefore result in less pain to the patient.

[00003] However, one common problem that has been found to exist with utilizing
15 thin lancets is the closure of the puncture site before an adequate volume of blood has been collected. Premature closure of the puncture requires additional blood to be drawn from the patient, often in a separate and sometimes less desirable location, resulting in an increase in pain and stress. Costs also increase, as multiple lancets are required to acquire an adequate sample.

20 [00004] Attempts have been made to provide lancing devices that inhibit premature closure of the puncture site. Such past attempts have included the use of an outer ring positioned away from the puncture site to "milk" or apply pressure around the wound to express a larger sample and prevent closure of the skin. Although utilizing the aforementioned circular ring often allows a larger sample to be collected before closure

of the puncture site, occasionally a sample size is still insufficient, and another lancing operation to collect blood or analytic fluid is required.

[00005] Thus it can be seen that needs exist for improvements to lancing devices to provide a mechanism that allows for an increased volume of blood or other analytic fluid to be expressed and collected before the puncture site closes. Needs further exist for such a mechanism that is readily adaptable to current lancing devices and procedures.

Summary of the Invention

[00006] In example forms, the present invention is an end cap for a lancing device that allows for an increased volume of blood or other body fluid to be collected from a lancing site on the skin of a human or animal subject. In example embodiments, the device compresses the skin's surface in a non-circular displacement region around the lancing site. In further embodiments, the device provides compression in a non-circular ring having a diameter smaller than the average outside diameter of the lancet, to prevent accidental discharge from or sticking of the lancet in the opening of the endcap.

[00007] In one aspect, the present invention is an end cap for a lancing device, the endcap having a non-circular opening through the tip to impart pressure upon the skin in an irregular compression zone around the lancing site.

[00008] In another aspect, the invention is an end cap having a non-circular opening sized and/or shaped to prevent sticking of the lancet body within the hole or passage of the lancet body through the hole.

[00009] In still another aspect, the invention is an end cap for a lancing device shaped to allow the lancet to be used at alternative sites on different regions of the subject's body. In yet another aspect, the invention is an end cap sized and/or shaped to prevent blood from contacting the lancing device during collection.

[00010] In still another aspect, the invention is a lancing device having a housing with an opening for passing a sharp lancet tip, the opening being lobed or non-circular, to interact with a greater surface area of skin surrounding the lancing site, for imparting pressure to milk a larger sample from the wound.

5 [00011] In another aspect, the invention is a method of increasing sample size from a lancing site, the method including the steps of lancing the skin of a human or animal subject to form a wound, and compressing a surface having a lobed or non-circular opening against the skin surrounding the wound.

[00012] These and other aspects, features and advantages of the invention will be
10 understood with reference to the drawing figures and detailed description herein, and will be realized by means of the various elements and combinations particularly pointed out in the appended claims. It is to be understood that both the foregoing general description and the following brief description of the drawings and detailed description of the invention are exemplary and explanatory of preferred embodiments of the
15 invention, and are not restrictive of the invention, as claimed.

Brief Description of the Drawings

[00013] FIGURES 1A and 1B show a perspective view of an end cap according to one example embodiment of the present invention.

[00014] FIGURE 1C shows a side view of an end cap according to one example
20 embodiment of the present invention having an axis A--A.

[00015] FIGURES 2A and 2B show a cross-sectional view of the end cap of Fig. 1 along cut-line A—A of Fig. 1C.

[00016] FIGURE 2C shows an end view of an exemplary embodiment of a non-circular opening in accordance with the present invention.

[00017] **FIGURE 3A** shows a frontal view of the end cap of Fig. 1, further defining region C.

[00018] **FIGURE 2B** shows a perspective view of region C in Fig. 3A.

[00019] **FIGURE 3C** shows an exemplary embodiment of the end cap of the present invention having a raised rim disposed around the non-circular opening.

[00020] **FIGURE 4** shows a preferred embodiment of an end cap in accordance with the present invention having a "star" shaped or multi-lobed opening.

Detailed Description of Example Embodiments

[00021] The present invention may be understood more readily by reference to the following detailed description of the invention taken in connection with the accompanying drawing figures, which form a part of this disclosure. It is to be understood that this invention is not limited to the specific devices, methods, conditions or parameters described and/or shown herein, and that the terminology used herein is for the purpose of describing particular embodiments by way of example only and is not intended to be limiting of the claimed invention. Also, as used in the specification including the appended claims, the singular forms "a," "an," and "the" include the plural, and reference to a particular numerical value includes at least that particular value, unless the context clearly dictates otherwise. Ranges may be expressed herein as from "about" or "approximately" one particular value and/or to "about" or "approximately" another particular value. When such a range is expressed, another embodiment includes from the one particular value and/or to the other particular value. Similarly, when values are expressed as approximations, by use of the antecedent "about," it will be understood that the particular value forms another embodiment.

[00022] With reference now to the drawing figures, an end cap 10 is shown by way of example embodiments of the present invention. As shown in Figures 1A-1C,

the end cap preferably is formed of a substantially rigid body 12 having an axis (A—A) extending from a first end 14 to a second end 16, wherein the first end 14 is sized and/or shaped to attach to a lancing device. The attachment of the end cap 10 to a lancing device can be accomplished by way of a releasable or permanent coupling
5 such as for example a threaded screw coupling, a socket, snap fittings, adhesive or welding, one or more screws or other connectors, or the like; or the endcap 10 can comprise an integral portion of the overall housing of the lancing device. In an example embodiment, at least a portion of the endcap 10 is formed of a transparent material to allow the patient and/or clinician to view the puncture site during lancing of the skin and
10 collection of the bodily fluid, and thereby monitor the sample size.

[00023] As shown in Figures 2A-2C, the second end 16 of the body 12 defines a non-circular opening 18 through which a sharp tip, such as a lancet tip, projects to lance the skin of the subject and form a wound at the sample site from which a sample of body fluid is expressed and collected. The non-circular opening 18 is preferably
15 defined by one or more inwardly directed lobes 20 extending from the second end 16 of the body 12. In further embodiments, additional lobes are used to further increase the surface area of the end cap that is applied to the skin. In still further embodiments, shapes which increase the tension of the end cap upon the skin are incorporated into the design. In one preferred form, the non-circular opening 18 is sized and/or shaped to
20 have an inside diameter that is smaller than the average outside diameter of the lancet to prevent “sticking” of the lancet body within the hole or passage of the lancet body through the hole. In further embodiments, the opening 18 is shaped to prevent bodily fluids blood from contacting the body 12 of the end cap 10 during lancing and subsequent collection.

[00024] With particular reference now to Figures 3A-3C, the lobes 20 are
25 optionally multi-planar (i.e., projecting inwardly and/or outwardly relative to a reference plane coincident with the overall forward surface of the endcap or the lancing device housing) to further increase the total skin surface area that can be captured and placed

in tension and/or compression during lancing and to continually apply surface pressure or intermittently pump the area surrounding the lancing site following lancing. In yet another embodiment, the opening 18 is surrounded by a raised rim 22 or one or more raised projections projecting outwardly from the body 12 to apply pressure upon the skin when lancing. In yet another embodiment, the non-circular opening 18 is flat. In various example embodiments, the opening 18 comprises an irregular or non-circular opening having one or more inwardly and/or outwardly projecting lobes or teeth for engaging the skin surrounding the lancing site. For example, and as seen best with reference to Fig. 2C, four inward lobes and four outward lobes are provided, relative to a reference circle 19 shown in broken lines. The lobes are depicted as having a smoothly-radiused curvature. In alternate embodiments, one or more inwardly and/or outwardly projecting teeth having sharp angles are provided in place of the lobes. It will also be understood that, while the depicted embodiment comprises four inward lobes and four outward lobes, alternate forms of the invention comprise one, two, three or more lobes and/or teeth to define an irregular or non-circular opening. Indeed, there are many different shapes, sizes and configurations, and/or combinations thereof, such as an end cap 10 having a "star" or "cross" shaped pattern, that are within the scope of the present invention, and will increase the surface area of tissue around the puncture site for contact and compression. It will also be understood that the invention encompasses a separate endcap for mounting to a lancing device, as well as a lancing device with an integral housing comprising an endcap portion thereof.

[00025] While the invention has been described with reference to preferred and example embodiments, it will be understood by those skilled in the art that a variety of modifications, additions and deletions are within the scope of the invention, as defined by the following claims.

CLAIMS

What is claimed is:

1. A lancing device comprising a lancet having a sharp tip and a body housing the lancet, wherein the body defines a non-circular opening through which the sharp tip projects to lance the skin of the subject.
2. The lancing device of Claim 1, wherein the non-circular opening is sized and/or shaped to have an inside diameter that is smaller than the average outside diameter of the lancet.
3. The lancing device of Claim 2 further comprising a raised rim around the non-circular opening for applying pressure to skin surrounding the lancing site.
4. An end cap for a lancing device, said endcap comprising a non-circular opening for allowing passage of a lancing tip therethrough.
5. The end cap of Claim 4 wherein the non-circular opening comprises a multi-lobed opening.
6. The end cap of Claim 5, wherein the non-circular opening is generally cross shaped, comprising four lobes.

7. A method for acquiring an increased volume of analytic fluid from a lancing site, the method comprising the steps of:
- providing a lancing device with an end cap defining a non-circular opening,
 - placing the lancing device against the skin so that the skin is in communication with the non-circular opening,
 - applying sufficient pressure on the lancing device to cause tension upon the skin within the non-circular opening,
 - triggering the lancing device, and
 - continuing to apply pressure upon the skin with the lancing device while fluid is extracted from the lancing site.

ABSTRACT

A tip portion or end cap for a lancing device having a non-circular opening to provide tension and pressure upon the patient's skin before and /or during lancing of the skin for sample collection. In exemplary embodiments, the end cap is shaped to prevent the lancet body from sticking within the hole or passing through the hole. The
5 end cap may also be shaped to allow it to be used at various lancing sites on the body without changing the end cap.

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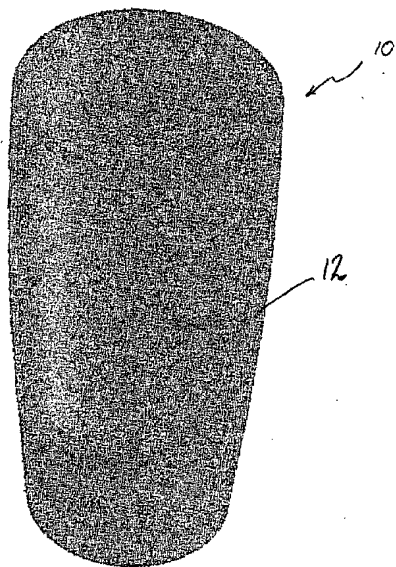


FIGURE 1A



FIGURE 1C

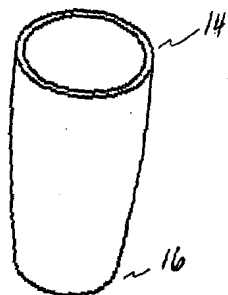


FIGURE 1B

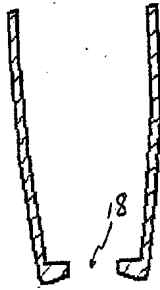


FIGURE 2A

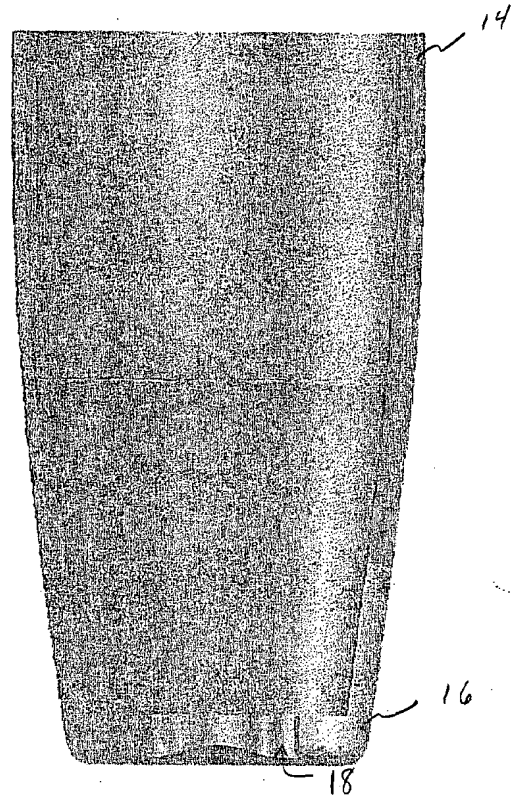


FIGURE 2B

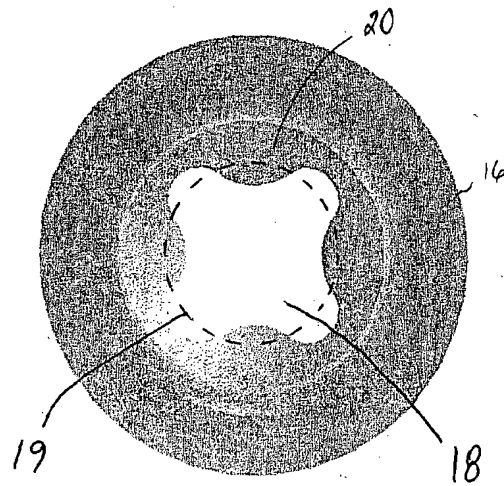


FIGURE 2C

3/4

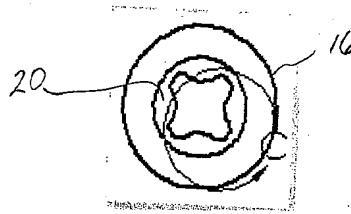


FIGURE 3A

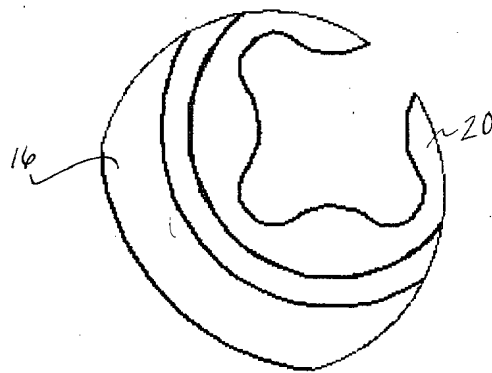


FIGURE 3B

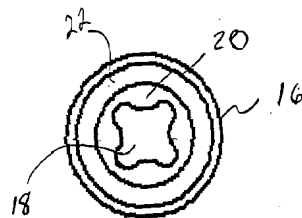


FIGURE 3C

4/4

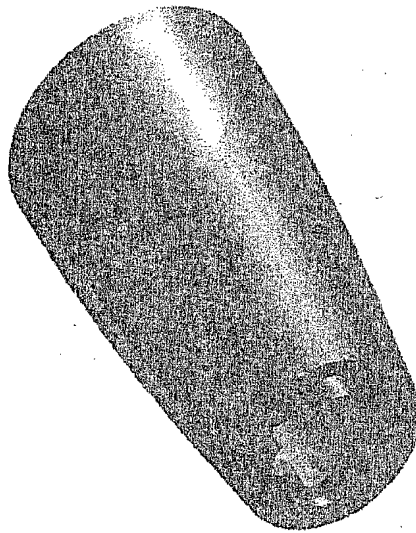


FIGURE 4